

## **REMARKS**

### **Status of the Claims**

Claims 21, 22, 24, 25 and 27-32 are currently pending in the application. Claims 1-13, 23-26 and 28-32 stand rejected. Claims 21, 22 and 27 are withdrawn as being drawn to a non-elected invention. Claims 21, 22, 24 and 28 have been amended as set forth herein. Claims 13-20, 23 and 26 have been cancelled herein. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendments to claims 21, 22, 24 and 28 are to change dependency from cancelled claim 13 to claim 28, and to address typographical errors concerning the identity of various sequences. Other amendments are to conform the claims more closely to US practice. Reconsideration is respectfully requested.

### **Interview**

Applicants and Applicants' representatives thank the Examiner for extending the courtesy of an interview on October 18, 2007. The substance of the interview is substantially as reflected in the Interview Summary of record. Briefly, during the interview, all issues barring allowance of the present claims were discussed. Particularly, a set of claim amendments proposed by Applicants were reviewed by the Examiner and discussed. The Examiner indicated agreement that if the proposed amendments to the claims were submitted, they would most likely address all outstanding rejections and most likely place the claims in condition for allowance. The Examiner should note that claim 13 has been cancelled herein without prejudice or disclaimer, thus addressing any possible issues remaining due to this claim language. Therefore, pursuant

thereto, Applicants submit herein the proposed claim amendments for entry into the record and consideration by the Examiner. Reconsideration and allowance thereof are respectfully requested.

### **Priority**

Applicants respectfully submit a certified copy of the priority document, JP 2003-038643 filed in Japan on February 17, 2003 under separate cover letter.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 13, 23-26 and 28-32 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (*See*, Office Action of July 27, 2007, at pages 4-6, hereinafter, "Office Action"). Claims 13, 23 and 26 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that the phrase "a diabody-type specific antibody according to claim 28" recited in claim 24 is indefinite because claim 28 is drawn to a diabody-type bispecific antibody. (*Id.* at page 5). Although Applicants do not agree that claim 24 is indefinite, to expedite prosecution, claim 24 has been amended herein without prejudice or disclaimer to recite "bispecific" instead of specific, to be more consistent with the language of claim 28.

The Examiner further states that claims 28-32 are indefinite because the terms "heavy chain" and "light chain" seem to be incorrect when referring to certain sequence identifiers. (*Id.*

at page 6). Although Applicants do not agree that claim 28 is indefinite, to expedite prosecution, claim 28 has been amended herein without prejudice or disclaimer to recite the correct identifying terms "light chain" and "heavy chain" where indicated. Applicants believe these changes address the Examiner's concerns.

Further regarding claim 28, the Examiner felt that the preamble of the claim was not entirely clear. (*Id.*). Again, although Applicants do not agree, the preamble of claim 28 has been amended without prejudice or disclaimer to recite, in part, "A humanized diabody-type bispecific antibody selected from the group of (A)-(D) consisting of ..." During the interview of October 18, 2007, the Examiner indicated that this language would most likely be acceptable in addressing this indefiniteness issue.

Claim 28 has been further amended without prejudice or disclaimer to recite "the amino acid sequence" as suggested by the Examiner at page 6 of the Office Action.

No specific reasoning is provided for the rejection of dependent claims 29-32. Therefore, dependent claims 29-32 are believed to be definite for, *inter alia*, depending from a definite base claim, amended claim 28.

Therefore, reconsideration and withdrawal of the indefiniteness rejection of claims 24, 25 and 28-32 are respectfully requested.

#### **Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 13, 23-26 and 28-32 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*See*, Office Action, at page 6). Claims 13

and 26 have been cancelled herein without prejudice or disclaimer thus obviating the rejection of these claims. Applicants traverse the rejection of the remaining claims as hereinafter set forth.

The Examiner states that the specification enables humanized diabody-type bispecific antibodies that comprise all six CDRs of the two parent antibodies but not species comprising less than all six CDRs. (*Id.* at page 7).

Applicants discussed this issue with the Examiner during the interview of October 18, 2007. During the interview Applicants explained the general concept of the presently claimed invention which is directed to single polypeptide chains that comprise a light chain with specificity for one epitope with a heavy chain with specificity for a second epitope, separated by a spacer. Thus, when such peptides are combined, they form two functional antibody binding sites, each binding a specific epitope.

Claim 28 is directed to pairs of such single polypeptide chains which together form two functional binding sites. The specification, in general, adequately supports such compositions since this is the subject matter of the present patent application. The Examiner stated during the interview on October 18, 2007 that upon further reflection on the specification, and in light of our discussions, any possible misunderstanding of the presently claimed invention was resolved.

Thus, reconsideration and withdrawal of the enablement rejection of claims 23-25 and 28-32 are respectfully requested.

**Rejections Under 35 U.S.C. § 102(b)**

Kipriyanov et al.

Claims 13 and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kipriyanov et al., *Protein Engineering*, 10(4):445-453, 1997 (hereinafter referred to as "Kipriyanov et al."). (See, Office Action, at page 9. Claims 13 and 23 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection of claims 13 and 23.

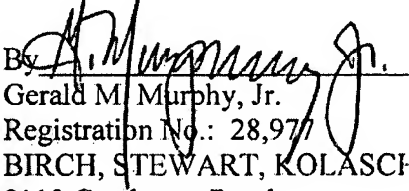
**CONCLUSION**

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: October 29, 2007  
(Monday)

Respectfully submitted,

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